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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,364	01/08/2004	Mitchell F. Brin	17641 (BOT)	7607

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STEPHEN DONOVAN
ALLERGAN, INC.
2525 Dupont Drive, T2-7H
Irvine, CA 92612

EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/754,364	BRIN ET AL.	
	Examiner	Art Unit	
	Lora E Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *5-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/3/04, 8/5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 12/21/04 is acknowledged. The traversal is on the ground(s) that searching all three claimed inventions would not present a burden to the Office. Applicant further elects botulinum toxin type A from the list in original claim 3, for example, but traverses the species election requirement on the basis that Schantz et al. (cited in applicant's prior action) disclose that the botulinum toxins are "a family of pharmacologically similar toxins."

The examiner disagrees on both counts. The inventions of Groups I, II and III are drawn to patentably distinct methods of using botulinum toxin, each with specific method steps and endpoints. Group II would necessarily require a different search than that required for Group I, as Group II recites a dilation effect that is not recited in Group I. Similarly, Group III is drawn to a method of treatment of a disease, which necessarily requires additional method steps, e.g. diagnosis of said disease and determining the outcome of said treatment. Searching Group III, therefore, requires a materially different search than that required for Group I. Searching all three inventions together would impose a serious burden on the examiner.

With regard to the species election, Schantz et al. disclose that while botulinum toxins are pharmacologically similar, they are distinct in important aspects. First, type A causes the most severe illness of the seven (p. 81, left hand column); additionally, the seven types of toxin bind to different acceptors and may have differences in their modes of action (p. 86, left hand column). Schantz et al. also describe numerous differences

among the botulinum toxin types in terms of pharmacology, activity, and effect on animals injected with each (p. 86-89). The toxin types are therefore patentably distinct.

The requirements are still deemed proper and is therefore made FINAL. The examiner notes that claims 5-12 have been cancelled. Examination will proceed at this point on amended claims 1-4 only.

Specification

Applicant is reminded of the proper content, language and format of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and **should include that which is new in the art** to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) **if a process, the steps.**

Extensive mechanical and design details of apparatus should not be given.

The abstract should be in narrative form (i.e. full sentences) and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be

avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The use of the trademark "BOTOX" has been noted in this application. It should be capitalized wherever it appears (e.g. at p.12, line 28) and be accompanied by the generic terminology. The use of the trademarks "MyoBloc" and "DysPort" has also been noted and should be formatted similarly.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Simulated or predicted test results and prophetic examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention that has not actually been conducted. Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have actually been achieved. **Paper examples should not be described using the past tense.** *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367, 66 USPQ2d 1385, 1394 (Fed. Cir. 2003). See M.P.E.P. 608.01(p) II. Examples 1-4 are interpreted by the examiner as being prophetic examples and should be amended as such.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a method for **treating improving** blood supply **through** a graft." It is not clear whether the claim is drawn to a method for treating a blood supply or to a method for improving blood supply. Additionally, the claim recites blood supply **through** a graft, which is confusing since the claim is broadly drawn to all grafts, even those that do not conduct blood. The claim also recites administering botulinum toxin to a blood vessel "at **or in the vicinity of** a graft," which is confusing. The word "vicinity" does not clearly define the metes and bounds of the claim, because it is not clear at what distance administration must be conducted with relation to the graft to be considered "in the vicinity" of the graft. Additionally, the claim recites "**administering** a botulinum toxin **to a blood vessel**," but it does not specifically point out the manner of administration, e.g. injection into the lumen of the vessel, application to the surface of the vessel, integration into the tissue of the vessel itself, or diffusion to the vessel from an injection point in nearby muscle. Finally, the claim recites "a **graft**", but it is not clear from the language of the claims which types of grafts to which the method is meant to improve blood supply. Clarification is required. Because claims 2-4 depend from indefinite claim

1 and do not clarify the point of confusion, these claims must also be rejected under 35 U.S.C. 112, second paragraph.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9 and 10 of Brooks et al. (2004, U.S. Patent 6,767,544; reference A) in view of Li (1994, U.S. Patent 5,376,376; reference B). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to methods with identical steps. U.S. '544 and the instant application each claim a method comprising the steps of administering botulinum neurotoxin directly into the wall of an artery. In some dependent claims, the botulinum neurotoxin is selected from types A, B, C, D, E, F and G; in some dependent claims, the botulinum neurotoxin is type A.

U.S. '544 teaches that the claimed method treats a cardiovascular disease; the instant application claims that the method improves blood supply through a graft.

Because the steps are the same, Brooks et al. are entitled to the same scope as the current application. Therefore U.S. '544 teaches the same process of administering botulinum toxin into the wall of an artery as in the current application, and thus the treated artery formed by U.S. '544 are one and the same as the treated artery formed in the current application.

Claim 1 of U.S. '544 recites that the administration of botulinum toxin should occur before carrying out "a coronary arterial cardiovascular procedure for reducing a coronary arterial blockage." U.S. '376 is cited as evidence that an autogenous saphenous vein graft is well known in the art as a procedure for reducing a coronary arterial blockage (column 1, lines 30-36). Claim 1 of U.S. '544 therefore encompasses instant claim 1.

Claims 1-4 are directed to an invention not patentably distinct from claims 1, 9 and 10 of commonly assigned U.S. Patent 6,767,544 (reference A). The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned claims, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the

invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. '544 taken in light of U.S. '376.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

U.S. '544 teaches injection of botulinum toxin A directly into an arterial wall of a patient (Examples 1-6). U.S. '376 is cited as evidence that an autogenous saphenous vein graft is well known in the art as a procedure for reducing a coronary arterial blockage (column 1, lines 30-36).

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger et al. (2003, U.S. Patent 6,579,847; reference C) taken in light of U.S. '376. The claims are drawn to a method as described above.

U.S. '847 teaches a balloon dilation catheter coated with botulinum toxin type A (Example 1; column 4, lines 13-17) and a method for using said catheter to administer the botulinum toxin to an artery wall (Example 5). U.S. '376 is cited as evidence that an autogenous saphenous vein graft is well known in the art as a procedure for reducing a coronary arterial blockage (column 1, lines 30-36).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SANDRA E. SAUCIER
PRIMARY EXAMINER

Lora E Barnhart

LEB